

EARTHRISE

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July 19, 2005

Susan J. Walker, M.D., Director,  
Division of Dietary Supplement Programs (HFS-810),  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration,  
Department of Health & Human Services  
5100 Paint Branch Parkway,  
College Park, MD 20740

RECEIVED  
JUL 25 2005

**Re: Notification of Structure/Function Statements –**  
**Earthrise® Spirulina IL-4® Dietary Supplement**

Dear Dr. Walker,

As per 21 CFR section 101.93, this letter is a notification of new structure/function claims to be made on labels, brochures and collateral materials of the following Earthrise Nutritionals dietary supplement: Earthrise® Spirulina IL-4® Capsules. The structure-function statements are listed on the enclosed attachment.

Manufacturer/Packer/Distributor: Earthrise Nutritionals, LLC.

The firm believes it has substantiation, and the structure-function claims are appropriate, truthful and not misleading. If you have any questions or concerns, please do not hesitate to contact me at (760) 348-5027 extension 321.

Sincerely yours,



Amha Belay, Ph.D.  
Senior Vice President/Scientific Director

2005-4862  
Aims

Enclosure

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July 19, 2005

**Structure/Function Statements For Earthrise Nutritionals, LLC.**  
**Earthrise® Spirulina IL-4® Dietary Supplement**

**Earthrise® Spirulina IL-4®: (Capsule)**

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**Ingredients:** Earthrise® Spirulina Gold® (*Arthrospira platensis*) and Vitamin C.

**Structure/Function Statements**

-A proprietary and advanced form of Spirulina which modulates the immune system.\*

-Inhibits IL-4 production.\*

-A human clinical study shows that this advanced form of Spirulina that is high in Zinc, Vitamin C and Phycocyanin reduces IL-4 (Interleukin-4), the mediator of IgE (Immunoglobulin E) production.\*

-A proprietary Spirulina product high in Zinc, Vitamin C and Phycocyanin to modulate the immune system while increasing antioxidant and anti-inflammatory protection.\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(The disclaimer appears in the appropriate places on labels and brochures).

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